REMARKS

I. Election / Restrictions

Although Applicants designated Claims 1-26 and 38-41 as readable on the elected species, Species 14 (Fig. 16), the Examiner unilaterally withdrew from consideration Claims 8-11, 16-23, and 25 as being drawn to a non-elected invention / species without providing any basis for doing so. Further, in view of the Examiner's withdrawal of additional claims, some of the remaining dependent claims are now incomplete and based on a withdrawn claim. Therefore, upon further review of the claims, Applicants respectfully request the Examiner's reconsideration and reinstate at least Claims 11, 17, 18, 19, and 20 in this case as readable on the elected species.

II. Drawings

Reconsideration is requested of the Examiner's objection under 37 C.F.R. 1.83(a) that the drawings fail to show the "supplemental support" of claims 13-15, 38 and 39. As explained in the last Response filed on or about December 21, 2004, in connection with claims 38 and 39, "additional stabilization" in the specification is the "supplemental support" in the claims. Therefore, Applicants respectfully refer the Examiner to the "connecting and stabilizing assembly 35" of Fig. 11A and the description related thereto clearly showing such "supplemental support" in the form of "clamping plate 36," "connecting rods 38," and "screws." Specification, p.18, lines 7-21. Therefore, Applicants believe the drawings already submitted in the application are in compliance with 37 C.F.R. 1.83(a) and that corrected drawing sheets are not necessary.

III. 35 U.S.C. §112 – Claims 13-15, 38 and 39; Claim 24

Reconsideration is requested of the Examiner's rejection of Claims 13-15, 38 and 39 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The Examiner takes the position that the "supplemental support" of these claims was not described in

the specification in such a way as to enable one skilled in the art to make and/or use the invention.

Applicants respectfully point the Examiner to Fig. 11A and the Specification p.18, lines 7-21, where the "additional stabilization" in the specification is the "supplemental support" in the claims, is described. Although the elected species of Fig. 16 is an artificial disc and Fig. 11A shows the "supplemental support" for a spinal cage, it is clear from a reading of the specification that Applicants intended, and as would be understood by one skilled in the art, that different features of the different embodiments are to be applied to the different embodiments. The specification supports such a reading because although different embodiments are shown, the specification describes all the embodiments as the "present invention" and describes the features as applicable to all these embodiments. See, e.g., Summary of Invention, p.6, line 8 – p.7, line 16 (emphasis added):

> SUMMARY OF INVENTION
>
> The present invention is an inter-space artificial disc implant utilized to replace a damaged disc. The present invention is clearly an improvement over the prior art providing an implant prosthesis intrinsically participating in this fusion process, self-stabilizing to the spinal segments, consistent with conventional methods of disectomy and uniquely and novel consistent with the preservation of the integrity of the adjacent vertebrae and their functionality.
>
> The present invention comprises an artificial disc implant for the purpose of which is to aid in and directly cause bone fusion at the bearing endplate surface portions of said device following the removal of a damaged disc. Said prostheses are biocompatible, structurally load bearing devices, stronger than bone, capable of withstanding the forces generated within the spinal inter-space. The bearing endplate surfaces have a plurality of openings of specific size which can be filled with fusion promoting material by inducing bone growth and osseous integration with the adjacent vertebrae forming a bony bond to the implants and each other. The implant bone-contacting surface may be textured, designed or otherwise treated by any known technologies to enhance and achieve bone in-growth and fusion to the implant's endplates to enhance stability of the implant and to expedite the fusion. The improved devices are configured and designed so as to promote their own stability within the vertebral inter-space to resist dislodgment, prevent micro-motion and stabilize the adjacent vertebrae.

> The present implant is made of a biocompatible material and has means if desired for increasing osseous integration, controlling hemostasis and preventing infection and controlling pain. It establishes proper spinal curvature or lordosis and kyphosis and capable of reducing a vertebral listness (a forward or backward translation of one vertebrae upon another as well as lateral misalignment of said vertebrae). It gives increased safety and precision which provides complete and easy visualization of the structures involved and adjacent vital structures (e.g. organs, neural structures and blood vessels and related bony surfaces). It also eliminates the need for a second surgical procedure to harvest bone. It also provides the method and material that is bio-resorbable and bio-compatible for **additional means of stabilization to be used in conjunction with the implant artificial disc prosthesis for certain conditions that require additional stabilization for osseous integration**. It may be used in distraction osteogenesis procedures in order to increase bone length and/or for inducing bone growth and osseous integration of the implant, and for controlling hemostasis and pain and preventing infection during and following the surgical procedure allowing for an increased opportunity of success.

Therefore, in view of the above, Applicants believe the enablement requirement under 35 U.S.C. 112, first paragraph is complied with.

Reconsideration is requested of the Examiner's rejection of Claim 24 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The Examiner takes the position that "a substance with anti-microbial drug eluting factors" of Claim 24 was not found in the specification.

Applicants respectfully point the Examiner to the Specification, p.11, lines 4-7 (emphasis added):

> It is another object of the present invention to provide a material having **anti-microbial factors** and method for preventing and controlling infection following the surgical procedure and said material may be **time released** locally and/or in combination with systemic drugs for this purpose.

The term "drug eluting" as known to one skilled in the art merely refers to the time release nature of the anti-microbial drug. However, Applicants has amended claim 24 to clarify the

terminology such that it now reads "time released anti-microbial factors" instead of "anti-microbial drug eluting factors." Therefore, Applicants believe this rejection is now moot.

IV. 35 U.S.C. §112 –Claim 24

Reconsideration is requested of the Examiner's rejection of Claim 24 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The Examiner takes the position that "a substance with anti-microbial drug eluting factors" of this claim was not described in the specification nor in the parent case, U.S. Patent No. 6,719,796, as to reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention.

Applicants respectfully point the Examiner to U.S. Patent No. 6,719,796, col. 5, lines 61-65 and Claim 16 (emphasis added):

> It is another object of the present invention to provide a material and method for **preventing and controlling infection** following the surgical procedure and said material may be **time released** locally and/or in combination with systemic drugs for this purpose.
>
> 16. The combination of a prosthesis and a substance comprising:
> (a) at least one set of first and second opposed bearing surface assemblies, each of said bearing surface assemblies having a substantially circular outer bearing surface, an inner face opposite to said outer bearing surface and a central axis through said outer bearing surface and said inner face;
> (b) each of said opposed bearing surfaces having a wall extending substantially normal and away from said inner face, said wall having a free end with at least one inclined cam surface, said inclined cam surface of said first bearing surface assembly cooperatively rests adjacent said inclined cam surface of said second bearing surface assembly;
> (c) means for rotating said bearing surfaces of said first and second opposed bearing surface assemblies co-axially towards and away from each other, said rotating means being integrated with the bearing surface assemblies, whereby relative rotation of said opposed complimentary bearing surface assemblies around said central co-axis by the rotating means in one direction will move the bearing surfaces of said first and second opposed bearing surface assemblies away from each other and relative rotation of said opposed complimentary bearing surface assemblies around said central co-axis by the rotating means in the

opposite direction will move the bearing surfaces of said first and second opposed bearing surface assemblies towards each other, thereby increasing and decreasing respectively, the height of said prosthesis along said central co-axis; and

(d) a substance with **anti-microbial drugs to control and prevent infection** adjacent to said bearing surface assemblies.

The ordinary dictionary meaning, and as understood by one skilled in the art, of the term "infection" means "invasion by and multiplication of pathogenic **microorganisms** in a bodily part or tissue ...." See, www.dictionary.com, a copy of which is attached hereto. Therefore, a material that prevents or controls infection is "anti-microbial." See, www.dictionary.com's definition for microbe as being a "microorganism," a copy of which is attached hereto. Therefore, the parent U.S. Patent No. 6,719,796, as cited above, clearly described to one skilled in the art the term "time released anti-microbial factors" of amended Claim 24.

Further, in rejecting Applicants' claims having the element a "substance with anti-microbial drug eluting factors," the Examiner relied on Shinn et al., U.S. Patent No. 5,683,465. See, § VII, infra. In his rejection, the Examiner admitted in the Office Action that it is "obvious to one having ordinary skill in the art [to use] an antibiotic as taught by Shinn et al or any other drug know [sic] in the art of prosthetics to promote healing, lessen the chances of infection ...." Therefore, as admitted by the Examiner, Applicants' description cited above more than adequately convey to one skilled in the relevant art that Applicants have possession of the claimed invention.

V. 35 U.S.C. §112 –Claims 24, 40 and 41

Reconsideration is requested of the Examiner's rejection of Claims 24, 40, and 41 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regards as the invention.

With respect to Claim 24, as discussed in §§III and IV, supra, the specification clearly explains the terminology "time released anti-microbial factors" of amended Claim 24. Therefore, this rejection is now believed to be moot.

With respect to Claims 40 and 41, these claims are amended to provide antecedent basis to "modular sets" and "means for connecting." Therefore, this rejection is now believed to be moot also.

VI. 35 U.S.C. §102 (Cauthen)

Reconsideration is requested of the Examiner's rejection of Claims 1-5, and 12-13 under 35 U.S.C. 102(e) as being anticipated by Cauthen, U.S. Patent No. 6,019,792. The Examiner relied on the Cauthen reference for disclosing all the elements of Claim 1, and relied on element 90 in Fig. 5 as the flexible supporting means.

The Cauthen reference discloses an articulating spinal implant comprises two hemicylindrical elements with a ball-and-socket joint between the two elements. Abstract. The Cauthen reference intended the ball-and-socket joint to resist axial compression and allows pivotal movement. Id.; Col. 2, line 66 – Col. 3, line 3; Col. 3, lines 23-27, 42-46; Claims 12 and 16. In one embodiment of the Cauthen reference, Fig. 5, a hemispherical bowl-shaped cap 90 having a generally uniform thickness and being relatively thin acts as an intermediate articulation element at the ball-and-socket joint between the two hemicylindrical elements. Col. 7, lines 32-39. Cap 90 is made of a low friction material to provide bipolar articulation to reduce frictional wear on the articulation surfaces. Col. 7, lines 42-49.

A claim is anticipated under 35 U.S.C. §102(e) only if "each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." Verdegaal Bros. V. Union Oil Co. of California, 814 F.2d 628, 631, 2 U.S.P.Q.2d

1051, 1053 (Fed. Cir. 1987) (emphasis added). Amended Claim 1 discloses an artificial disc for placement between adjacent vertebrae comprising:

> at least two ***plate members***, each plate member having a corresponding surface;
>
> at least one means for temporarily stabilizing said plate members for a certain period of time to allow at least two of said plate members to osteo-integrate with adjacent vertebrae; and
>
> at least one flexible supporting means interposed between said plate members and abutting said corresponding surfaces, ***said flexible support means flexibly and compressibly supporting said plate members*** after said certain period of time.

The Cauthen reference fails to disclose, teach or suggest at least the above elements of amended Claim 1 as shown in ***bold and italics*** above. A "plate member" is substantially uniformly flat. The plate members of the present invention advantageously provide sufficient surface area to contact the adjacent vertebrae and to allow the plate members to osteo-integrate with adjacent vertebrae. The hemicylindrical elements of the Cauthen reference, which provide minimal contact with adjacent vertebrae, are patentably distinct from and inferior to the plate members of the present invention

Further, Applicants believe that it is advantageous to provide an artificial disk that compresses with minimal pivotal movement. The flexible supporting means of the present invention advantageously compresses, as shown in Fig. 16 and discussed in the Specification, p.13, lines 13-14, emphasis added (The disk 102 may be made of titanium or some other known material which is biocompatible and compressible). The relative thickness and size of disc 102 with respect to the plate members provide sufficient compression of the artificial disc with minimal relative pivotal movement of the plate members. Throughout the specification, Cauthen teaches against a compressible spinal implant and repeatedly stresses the importance of resisting axially compression of the spinal implant. See, Abstract; Col. 2, line 66 – Col. 3, line 3; Col. 3,

lines 23-27, 42-46; Claims 12 and 16. Although cap 90 of the Cauthen reference "may be somewhat resilient to absorb impact loading" (col. 7, lines 39-42), such minimal resiliency, in view of the relatively thin and uniform thickness of cap 90, provides minimal, if any, compression. Further, the minimal thickness of cap 90 cannot withstand the typical compression rate of over 100 million motion cycle for a fifty-year life span. As disclosed and intended by Cauthen, cap 90 merely provides bipolar articulation without axial compression. Therefore, the Cauthen reference intentionally fails to teach "each and every element" of amended claim 1 and all claims dependent therefrom, as required under a §102(e) rejection.

VII. 35 U.S.C. §103 (Cauthen in view of Shinn)

Reconsideration is requested of the Examiner's rejection of Claims 24 and 14-15, 38 and 39 under 35 U.S.C. 103 as being unpatentable over Cauthen, U.S. Patent No. 6,019,792, in view of Shinn et al., U.S. Patent No. 5,683,465. The Examiner relied on the Cauthen reference for disclosing all the elements of the rejected claims and admitted that the Cauthen reference failed to disclose a "substance with anti-microbial drug eluting factors" and relied on the Shinn reference for disclosing this element.

As argued in §VI, supra, the Cauthen reference fails to disclose, teach or suggest all the element of amended Claim 1. Similarly, the Shinn reference also does not disclose, teach or suggest a "***flexible support means flexibly and compressibly supporting said plate members***" of the present invention. Therefore, amended Claim 1, and all claims dependent therefrom, are not unpatentable over the Cauthen reference in view of the Shinn reference.

VIII. 35 U.S.C. §103 (Cauthen in view of Gauchet)

Reconsideration is requested of the Examiner's rejection of Claims 4, and 6-7 under 35 U.S.C. 103 as being unpatentable over Cauthen, U.S. Patent No. 6,019,792, in view of Gauchet

et al., U.S. Patent No. 6,733,532. The Examiner relied on the Cauthen reference for disclosing all the elements of the rejected claims and admitted that the Cauthen reference failed to disclose a "flexible disc [having] opposed convex surfaces" and relied on the Gauchet reference for disclosing this element.

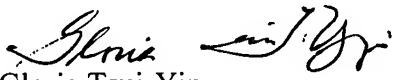
As set forth in M.P.E.P. §706.02(j), to establish a prima facie case of obviousness, the Examiner must meet three basic criteria. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991).

As discussed in §VI, supra, the Cauthen reference intentionally teaches a spinal implant that resists axial compression. However, the Gauchet reference discloses a prosthesis that compresses. The prostheses disclose in the Cauthen and Gauchet references are distinct in purpose and structure and cannot be combined in a §103 rejection because one reference teaches something against what the other reference teaches. There is no suggestion or motivation in either reference to modify the device to provide or not provide compression of the other reference other than hindsight obtained after reading Applicants' specification. Therefore, it is improper, under M.P.E.P. §706.02(j) to combine the Cauthen and Gauchet references and it would not be obvious to one skilled in the art to utilize the opposed convex surfaces configuration taught by the Gauchet reference in the device of the Cauthen reference.

IX. Conclusion

By virtue of the amendment of the claims as well as the Applicants' remarks thereto, all outstanding grounds of rejection and objection have been addressed and dealt with and, based thereon, it is believed that the application is now in condition for allowance and such action is respectfully solicited.

Respectfully submitted,



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